

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problems Mailbox.**

SIN 09/702, 423
Group 3227
11/8/85

(12) UK Patent Application (19) GB (11) 2 031 735 A

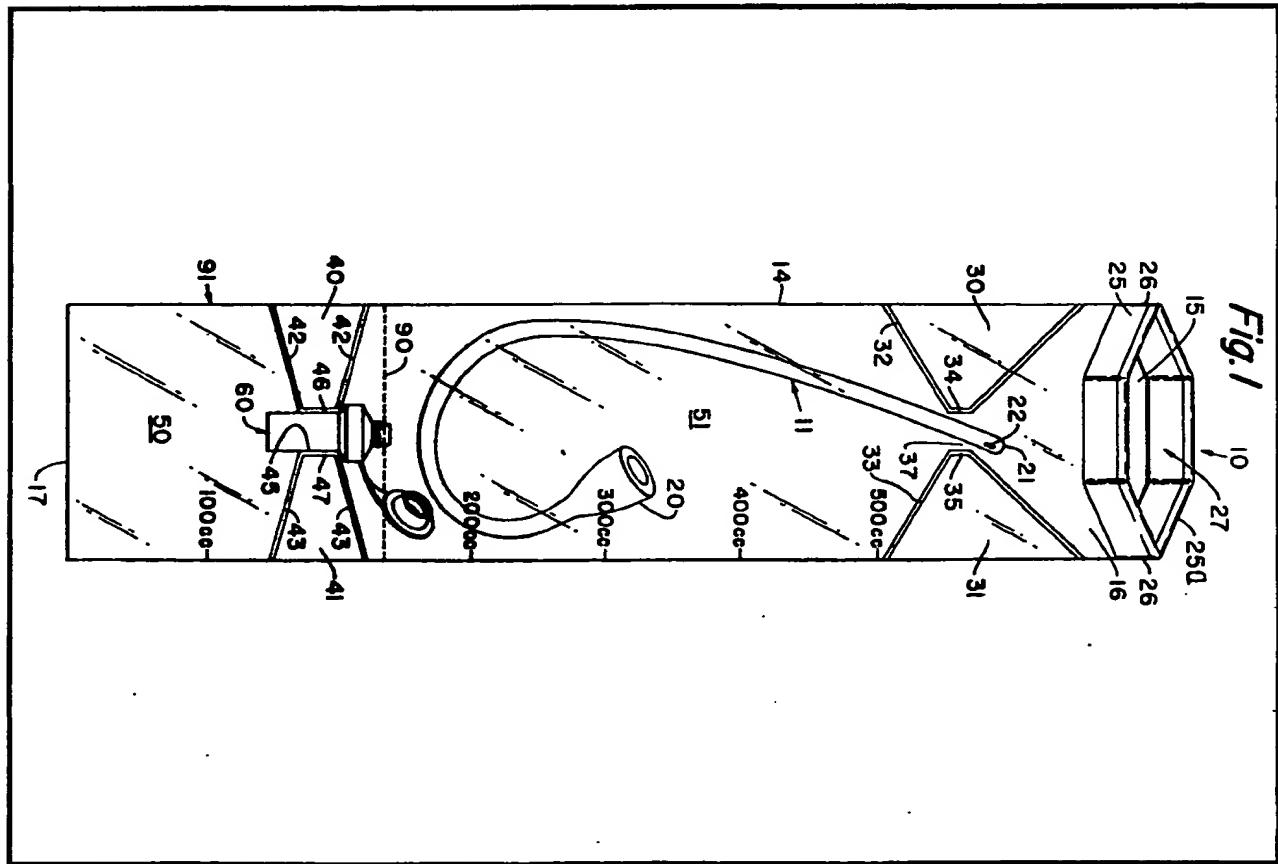
(21) Application No 7934031
(22) Date of filing
1 Oct 1979
(23) Claims filed
1 Oct 1979
(30) Priority data
(31) 947961
(32) 5 Oct 1978
(33) United States of America
(US)
(43) Application published
30 Apr 1980
(51) INT CL³ A61M 25/00
(52) Domestic classification
A5R CE
(56) Documents cited
GB 1418176
(58) Field of search
A5R
(71) Applicants
Rehabilitation Institute
of Chicago
345 East Superior
Street
Chicago
Illinois 60611

United States of
America
Illinois Tool Works Inc.
8501 West Higgins
Road
Chicago
Illinois 60631
United States of
America
(72) Inventors
Yeongchi Wu
Roger Alan Erber
(74) Agents
Gill Jennings & Every

(54) Improved disposable urethral catheter assembly

(57) A disposable urethral catheter assembly includes a flexible bag 14 in which a number of chambers are defined by barriers. In an upper chamber 51, a catheter 11 is contained in a sterile environment. When the catheter is inserted

through the urethra into the bladder, the fluid flows into the bag through the upper chamber and into a lower sample chamber 50, excess fluid being collected in the upper chamber. After catheterization, a one-piece element 60 which provides a sealable passageway through the first barrier 40, 41 between the upper and lower chamber can be readily closed by manipulation through the wall of the bag and thus isolate the sample in the lower chamber. The upper chamber, its contents and the catheter are separated from the sealed lower chamber and discarded. The lower sample chamber 50 which provides a sterile environment for its contents can then be sent to a laboratory for analysis and culture.



2031735

1/2

Fig. 1

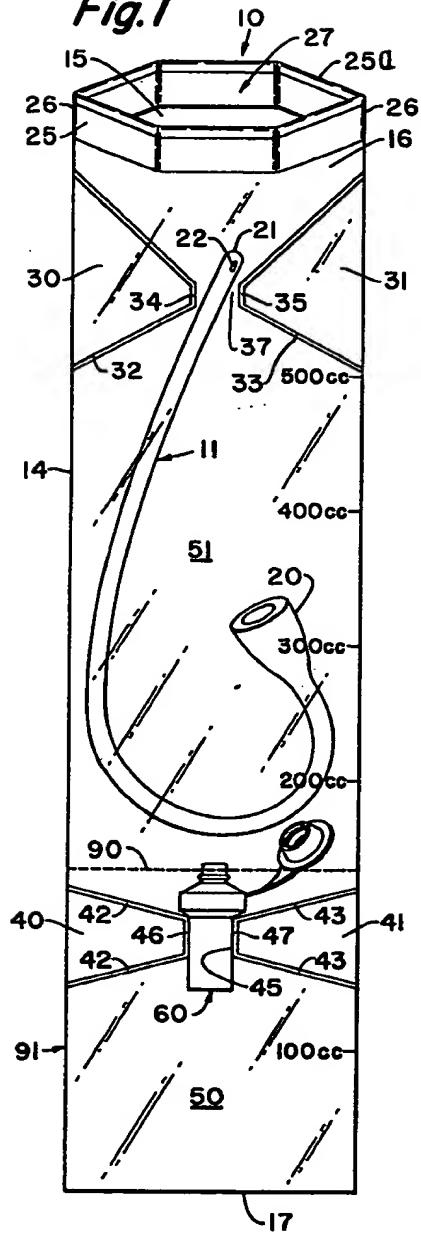
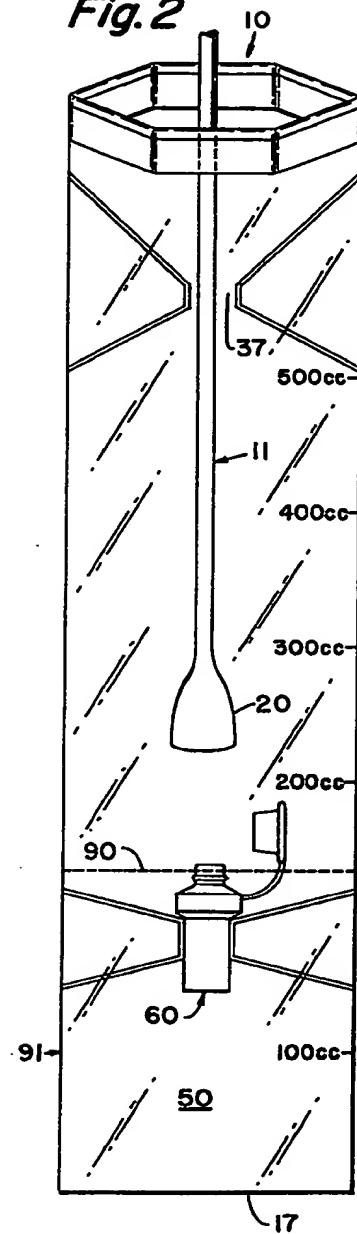


Fig. 2



2031735

2/2

Fig. 3

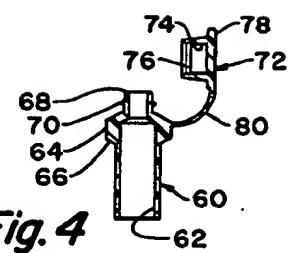
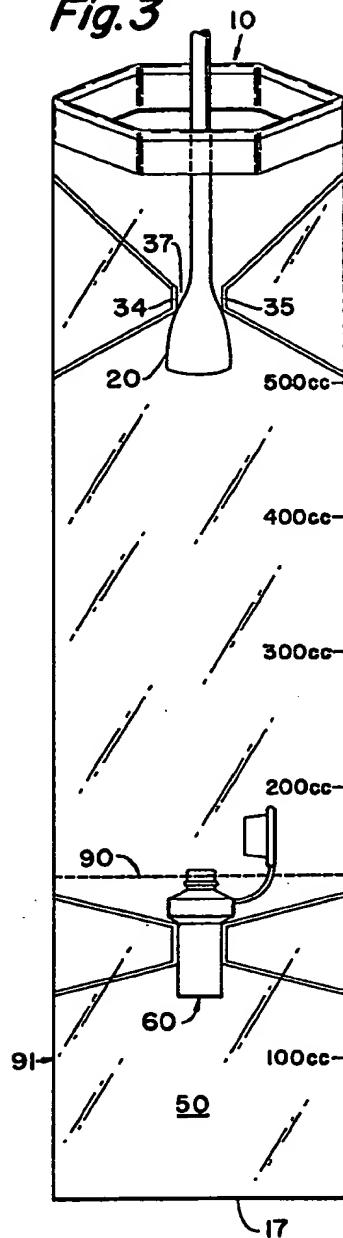


Fig. 4

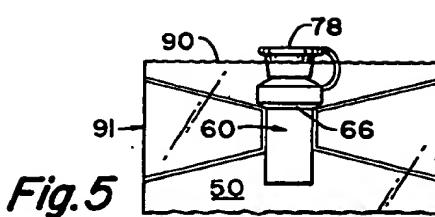


Fig. 5

SPECIFICATION

Improved disposable urethral catheter assembly

5 *Background of the Invention*

This invention relates generally to fluid collectors for use with catheters and related apparatus, and more particularly concerns a catheter fluid collector device which more or less automatically isolates a fluid sample for later laboratory study, including urinalysis and culture and sensitivity tests.

Many victims of paralysis are unable to 15 voluntarily evacuate their bladder. These persons must be catheterized periodically in order to remove accumulating body waste fluids.

A number of non-surgical and semi-surgical techniques and related devices have been 20 offered to perform this catheterization. For male patients this procedure in general involves aseptically preparing the penis, and then inserting a catheter into the urethra, while maintaining sterile technique, until the 25 eye of the catheter reaches and communicates with the bladder. Urine then flows through the catheter and can be directed into a collection container or disposal device.

If a urine specimen is required for medical 30 analysis, the urine flow from the catheter is directed into a specimen collection container until an adequate sample is collected; remaining portions of the urine flow are then directed back into the disposal structure. When 35 the bladder has been emptied and the procedure completed, the catheter is removed and disposed of, and the specimen container is sealed and sent to a laboratory for microbiological and biochemical studies.

40 At least some of these techniques and their associated implements offer the dangers of urethra contamination during procedure preparation, catheter contamination during handling, and specimen contamination during 45 specimen container filling, sealing and emptying. Many of the techniques and associated apparatus must be performed in a semi-surgical setting; they cannot be conveniently performed by the patient himself while he is 50 alone and in a semi-private washroom or other location.

Additionally, when collector bags or receptacles are provided, some catheterization apparatus permit inadvertent removal of the 55 catheter from the collector, thus presenting the possibility of accidental spillage and attendant mess. Such an occurrence can cause discomfort and even humiliation to the patient.

60 It is accordingly the general object of the present invention to provide a urine collector which is handy and safe to use, and which more or less automatically containerizes a urine sample for laboratory analysis.

65 A fluid collector according to the present

invention includes a urethral catheter for delivering a quantity of liquid from a human body, and a flexible bag containing the catheter prior to catheter use, said bag including first

70 barrier means defining at least a first chamber capable of containing a predetermined volume of liquid and a second chamber capable of containing the liquid delivered from said body in excess of the liquid deposited in said first

75 chamber, said collector further including a permanently positioned one-piece means defining a sealable passageway through said first barrier to provide controlled egress between said first and second chambers.

80 The accompanying drawings show one example of a collector embodying the present invention.

Brief Description of the Drawings

85 Figure 1 is an elevational view of the novel collector and catheter as they appear when ready for use;

Figure 2 is an elevational view similar to Fig. 1 showing the catheter and collector as 90 they appear when the catheter is being inserted into the urethra;

Figure 3 is an elevational view similar to Figs. 1 and 2 and showing the collector and catheter as they can appear when the catheter 95 has been relatively fully inserted and is about to deliver a quantity of fluid to the collector;

Figure 4 is a sectional elevational view of the one-piece element forming the sealable passageway through the barrier defining the 100 two chambers in the bag; and

Figure 5 is an elevational view of a collector first chamber which has been filled with fluid, sealed by closure of the one-piece element, separated from the balance of the bag and 105 ready for removal to a laboratory for analysis.

Detailed Description

While the invention will be described in connection with a preferred embodiment and 110 procedure, it will be understood that it is not intended to limit the invention to this embodiment or procedure. On the contrary, it is intended to cover all alternatives, modifications and equivalents as may be included

115 within the scope of the invention and defined by the appended claims. For example, this collector device and procedure can be used, with suitable minor modifications, by female as well as male patients.

120 Turning first to Fig. 1, there is shown the novel collector 10 and catheter 11 embodying the present invention. Here the collector takes the form of a transparent flexible bag 14 made of a suitable polymeric film such as any

125 of the appropriate polyolefins, polystyrenes or the like. The bag can be of an elongated form, as illustrated, and is defined by two folded or otherwise opposed material layer films 15 and 16 sealed at the bottom 17 and 130 may also be sealed at the top 25a with a

suitable tear seal. Such sealing of top 25a can be used in the event the collector is not packaged in a secondary sterile container or envelope. It is contemplated that the bag

5 interior will be rendered sterile by appropriate operations during manufacture.

The catheter 11 can be considered to comprise an elongated hollow tube 19 terminating at one end in an enlarged or bulbous discharge end 20. At an opposite tip 21, an eye or perforation 22 communicates with the hollow tube interior, as is well known in the art of urethra catheters. The catheter, too, is rendered sterile during manufacturing.

10 After manufacturing production and prior to use, the catheter 11 is carried in a sterile environment. To this end, the bag 14 is provided with a closure top 25. If desired, a resilient member within the closure top 25

15 can be biased into an open position from its normally closed position by squeezing opposite edges 26 toward each other to provide an irregular, hollow, polygonal opening and chamber 27 for accommodating the head of a

20 male penis. This top chamber 27 is at least partly defined by two upper chevrons 30 and 31 formed within and upon the bag, as by heat sealing narrow bands 32 and 33 of one bag side 15 against the opposite bag side 16.

25 In use, the urethra orifice and head of the penis is asepticized. The bag top 25 is then opened by tearing seal 25a and squeezing edges 26, thereby exposing and forming the top chamber 27. A suitable lubricant is added

30 to top chamber 27 and the penis glans is inserted into chamber 27 until it contacts chevrons 30 and 31 thereby orienting and aligning the urethra with the opening 37. The bag 14 and catheter 11 are then manipulated

35 so as to extend the catheter 11 out from the top of the bag, as illustrated in Fig. 2. In accordance with one aspect of the invention, this procedure eliminates the need for directly touching the catheter 11, for the bag opening

40 27 is adapted to be brought over the penis head. Since the interior of the opening 27 is aseptic, catheterization procedure sterility is encouraged.

45 It will be noted that these upper chevrons 30 and 31 extend toward one another, but terminate at truncations 34 and 35, respectively which define a restricted opening 37 through which the catheter tube 19 extends. To discourage inadvertent catheter removal,

50 the opening 37 is reduced in size relative to the enlarged catheter bulbous end 20 whereby end 20 cannot be inadvertently pulled through, as particularly illustrated in Fig. 3. When male patients use the novel device, the

55 catheter can be gripped through the bag with the forefinger and thumb of one hand while the penis is held against the chevrons 30 and 31 inside the bag top cavity 27. The patient or user eases the catheter tube 19 into the

60 urethra orifice and into the urethra itself with

succeeding gripping and releasing motions, allowing the plastic bag 14 to first corrugate and then to relax into its original position after each movement. In this way, the catheter is

65 inserted into the urethra until the catheter tube opening or eye 22 enters the bladder and urine begins flowing into the bag. Urine flow is permitted until a substantial portion of the bladder has been evacuated. When catheterization has been completed, or when the maximum acceptable volume has been received in the bag, the patient or user removes the catheter and bag in one outward motion.

A urine sample of convenient volume for

70 laboratory analysis is more or less automatically collected by this device and procedure. To this end, two lower chevrons or barriers 40 and 41 are formed within and upon the bag, as by heat sealing the bag sides 15 and 16 to

75 one another along outwardly diverging lines 42 and 43 respectively. A relatively narrow opening 45 is defined between two opposed heat sealed lines 46 and 47. To maintain a free passage through the barrier formed by

80 chevrons 40 and 41 there is provided a one-piece sealable tubular element 60. In prior art collector units, such as shown in application for U.S. Patent, Serial, No. 831,701 filed September 12, 1977, a moveable cannula

85 plug was located in the lower chamber 50. It was necessary to manipulate such a plug within the bag to align it with the narrow opening 45 and then move the plug axially to

90 seal the passageway. This was found to be a difficult and often distasteful operation due to spillage of liquid from the upper reservoir 51. On many occasions the manipulation operation resulted in pin-holes being formed in the bag resulting in leakage from the bag and

95 contamination of the aseptic conditions.

To overcome these difficulties the present invention utilizes a one-piece tubular element 60 having a through bore 62, an enlarged portion 64 forming a shoulder 66 and a

100 reduced necked-down portion 68, the latter, in this embodiment, having an annular ring 70 located intermediate the extremities of portion 68. Integrally attached to element 60 is a sealing cap 72 having a closed bore 74

105 with an annular groove 76, the bore and groove being complementary to portion 68 and ring 70. The closed end of cap 72 may include a lateral flange 78 to which is attached one end of a hinge-like strap 80 which

110 is connected at the opposite end to the enlarged portion 64 of element 60.

During fabrication of the collector 10, the element 60 is positioned and immobilized by the heat sealing of chevrons 40 and 41 with

115 the shoulder 66 formed by enlarged portion 64 locating element 60 relative to the diverging lines 42 and 43 and further acting as a reactant to the force of the liquid pressure or head formed when reservoir 51 is filled as

120 well as when cap 72 is moved into closed

sealing relation with portion 64.

In the operation of the collector 10 the tubular element 60 with the cap in its open position permits a predetermined quantity of fluid to flow into the specimen reservoir, in this embodiment the lower or first chamber 50. When the first chamber 50 is filled, additional fluid accumulates in a relatively upper or second chamber 51. The total volume of fluid material collected can be determined with reasonable accuracy by a volumetric measurement scale marked upon the bag when the bag is held in a vertical position, as indicated in Figs. 1 through 3.

If a specimen is desired the cap 72 is manipulated through the bag into a closed position, as seen in Fig. 5, the top or second chamber 51, the catheter 11, and other portions of the device can be discarded, in further accordance with the invention. To do this, the entire device 10 is preferably removed to a disposal area, where the fluid in the second or top chamber 51 is emptied. The patient or attendant then removes the catheter 11 and top portion of the bag 14, as by tearing or cutting along a convenient sever line 90 which can be marked upon the bag. The lower portion 91 of the device, including the filled and sealed first chamber 50, can then be transmitted to the laboratory for urine analysis and culture and sensitivity tests together with desired identifying data, such as the patient's name and any hospital room number.

In the laboratory, a laboratory technician removes the cap portion 72 from the element 60. After the fluid sample is dispensed and tests have been completed, the device lower portion 91 and any unused fluid can also be discarded, thereby eliminating any need to undertake costly re-sterilization procedures.

CLAIMS

1. A fluid collector including a urethral catheter for delivering a quantity of liquid from a human body, and a flexible bag containing the catheter prior to catheter use, said bag including first barrier means defining at least a first chamber capable of containing a predetermined volume of liquid and a second chamber capable of containing the liquid delivered from said body in excess of the liquid deposited in said first chamber, said collector further including a permanently positioned one-piece means defining a sealable passageway through said first barrier to provide controlled egress between said first and second chambers.

2. A fluid collector according to Claim 1 wherein said bag is an elongated rectangle formed of a transparent flexible polymeric film.

3. A fluid collector according to Claim 1 wherein said first barrier means includes two opposed chevron formations formed in and on

said bag.

4. A fluid collector according to Claim 3 wherein said chevron formations each include a chevron defined by line portions of said bag 70 heat sealed to an adjacent but opposed portion of the bag.

5. A fluid collector according to Claim 4 wherein said chevrons take the form of opposed trapezoids.

75 6. A fluid collector according to claim 3, wherein said one-piece means includes a pass-through tubular element having external means cooperating with said chevron formation to maintain said element in substantially 80 fixed relation relative to said barrier.

7. A fluid collector according to claim 6, wherein said tubular element is enlarged adjacent one end to provide shoulder means for engagement with said chevron formation to 85 prevent movement through said barrier into said first chamber.

8. A fluid collector according to claim 7, wherein said enlargement tapers inwardly at said one end to a neck, including a cap 90 integrally connected to said tubular element and adapted to sealingly cooperate with said neck to close egress through said tubular element.

9. A fluid collector according to claim 8, 95 wherein said cap is connected to said tubular element by a strap which permits manipulation of said cap from an open to a closed position through the closed walls of said bag, whereby a specimen sample of the liquid from 100 said body can be retained in said first chamber while the liquid in said second chamber is disposed of after withdrawal of said catheter from said body.

10. A fluid collector according to claim 1, 105 including second barrier means separating said second chamber at least partially from an adjacent portion of said bag, said second barrier means having a central passageway adapted to permit passage therethrough at at 110 least part of said catheter.

11. A fluid collector according to claim 9, wherein said catheter is equipped with stop means preventing complete withdrawal of the catheter from the second chamber.

115 12. A fluid collector according to claim 10, wherein said catheter stop means comprises an enlarged catheter end for abutment against said second barrier means when withdrawal of said catheter from said chamber is 120 attempted.

13. A fluid collector including, in combination, a volume-calibrated, internally sterile elongated flexible bag and a urethral catheter contained therein, the lower portion of said 125 bag including a first barrier means formed by opposed heat sealed chevrons forming a fluid specimen reservoir of predetermined volume, a one-piece tubular element having a movable sealing closure at one end, said element positioned and retained between said chevrons to

- provide controllable access to said reservoir,
said bag further including a second set of heat
sealed opposed chevrons adjacent the top of
said bag to define a channel communicating
5 between the ambient open end of said bag
and a second reservoir defined by said bag
between the first and second sets of chevrons,
said catheter initially being located in said
second reservoir and adapted to be extended
10 through said channel during catheterization.

13. A fluid collector according to claim 1,
substantially as described with reference to
the accompanying drawings.

Printed for Her Majesty's Stationery Office
by Burgess & Son (Abingdon) Ltd.—1980.
Published at The Patent Office, 25 Southampton Buildings,
London, WC2A 1AY, from which copies may be obtained.